In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 20-1358V UNPUBLISHED

KATHERINE CUMMINGS and JARED CUMMINGS, Parents of O.C., a Minor,

Petitioners,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: February 24, 2022

Special Processing Unit (SPU);
Findings of Fact; Statutory Six Month
Requirement Measles Mumps
Rubella (MMR) Vaccine; Varicella
Vaccine; Diphtheria Tetanus acellular
Pertussis (DTaP) Vaccine;
Haemophilus influenzae type b (Hib)
Vaccine; Hepatitis A (Hep A)
Vaccine; Pneumococcal Conjugate
Vaccine; Thrombocytopenic Purpura
(ITP)

Emily Beth Ashe, Anapol Weiss, Philadelphia, PA, for Petitioners.

Kyle Edward Pozza, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT1

On October 9, 2020, Katherine and Jared Cummings, parents of O.C., a minor, filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq.² (the "Vaccine Act"). Petitioners allege that O.C.

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioners have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

received the varicella, DTaP, hemophilus influenza B, hepatitis A, MMR, and pediatric pneumococcal vaccines on March 7, 2019 and thereafter was diagnosed with idiopathic thrombocytopenic purpura ("ITP"), which was caused by these vaccines. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

For the reasons discussed below, I find that it is more likely than not that O.C. suffered the residual effects of ITP for more than six months – although the issue is extremely close.

I. Relevant Procedural History

Petitioners filed Exhibits 1-4 containing medical records on November 9, 2020 (ECF No. 7). On November 20, 2020, Petitioners filed Exhibit 5, an affidavit (ECF No. 9). On June 24 and August 11, 2021, Petitioners filed Exhibits 6 and 7 containing medical records (ECF Nos. 18 and 23).

On January 28, 2022, Respondent filed his Rule 4(c) Report and Motion to Dismiss (ECF No. 28). In the report, he asserted that the statutory severity requirement had not been met and the case should be dismissed. On February 11, 2022, Petitioners filed a response.

On February 17, 2022, a telephonic status conference was held to discuss the parties' submissions and how the parties wished to proceed. Emily Ashe appeared on behalf of Petitioners, and Kyle Pozza appeared on behalf of Respondent. During the conference, counsel for both parties stated that they did not wish to file additional evidence or briefing, and agreed that the issue of whether O.C. suffered the residual effects of ITP for more than six months was ripe for resolution.

II. Issue

At issue is whether O.C. continued to suffer the residual effects of ITP for more than six months. Section 11(c)(1)(D)(i) (statutory six-month requirement).

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy

evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of

the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make these findings after a complete review of the record, including all medical records, affidavits, Respondent's Rule 4 Report, Petitioners' response, and additional evidence filed:

- Exhibit 1 at 85-87, recording that on March 7, 2019, O.C. received MMR, Pneumococcal, Hepatitis A, DTaP, HIB, and Varicella vaccines.
- Exhibit 2 at 74-80, a record of O.C.'s March 31-April 2, 2019 hospitalization, during which she was diagnosed with ITP that was noted to have occurred three weeks after vaccination. Four days prior to her hospitalization, i.e., March 27, 2019, O.C. had two injuries where she hit her left temple and forehead. Ex. 2 at 76. O.C. presented with "[e]xtensive bruising, including forehead hematoma" and several smaller contusions on her back and extremities, in addition to gingival bleeding.³ *Id.* at 74, 77. Testing revealed a platelet count of less than 1,000/mm. Ex. 1 at 95. O.C. was subsequently assessed with severe ITP. Ex. 2 at 52, 57.
- Exhibit 2 at 4, 77, documenting that during her hospitalization for ITP, O.C. was given intravenous methylprednisone on March 31 and April 1, 2019, and oral prednisone thereafter. On the third day of O.C.'s hospitalization, her platelet count had increased from undetectable to 84,000/mm. *Id.* at 77. By the time of discharge on April 2, 2019, the bruising along O.C.'s forehead had decreased in size and swelling. *Id.* She was discharged with a four-day course of steroids. *Id.*

4

³ The hospital record contains pictures of O.C. at the time of hospitalization. See Ex. 2 at 43, 45, 47, 308.

- Exhibit 2 at 58, a March 31, 2019 treatment plan stating that O.C. should be monitored closely for bleeding and should "[l]imit activity due to high risk of bleeding."
- Exhibit 2 at 79, April 2, 2019 discharge instructions indicating that O.C. "needs to be protected from injury as much as possible" and "should not take part in contact sports unless directed by [her] physician."
- Blood testing performed in April 2019 revealed platelet counts that varied, from below 100,000/mm to above 200,000/mm – and the levels continued to fluctuate into May. Ex. 1 at 116-121.
- Exhibit 2 at 226, a record of a June 1, 2019 emergency department visit indicating that O.C. was experiencing "continued bruising but normalizing platelet count" and indicating that O.C. should be "discharge[d] home with precautions." O.C.'s platelet count was 106,000/mm, below the normal range. *Id.* at 240.
- Exhibit 2 at 294-96, a record of a July 19, 2019 visit with hematologist Dr. Keri Streby, indicating that O.C. was doing well clinically with no bleeding or bruising noted by family. O.C.'s platelet count was 131,000/mm which was below normal. *Id.* at 262. Dr. Streby ordered that her platelet counts continue to be checked monthly for the next few months. *Id.* at 264.
- Exhibit 1 at 129, laboratory results from August 19, 2019, recording that O.C.'s platelet count was now 121,000/mm still below the normal range (140,000/mm to 400,000/mm).
- Exhibit 3 at 105 and 1 at 131, laboratory results from October 11, 2019, recording that O.C.'s platelet count was now 187,000/mm, which is within the normal reference range of 140,000/mm to 440,000/mm, although on the lower end.
- O.C. had a well-child pediatric visit on September 16, 2019, at which time her ITP was not discussed, and there is otherwise no record evidence of blood testing performed that month. Ex. 4 at 4.
- Exhibit 3 at 105, an October 11, 2019 note of treating physician Dr. Streby, characterizing O.C.'s platelet level of 187,000/mm as "almost normal," and thus suggesting that the physician did not view O.C.'s condition as having

fully resolved. At this time, Dr. Streby ordered that O.C.'s platelet counts continue to be checked monthly. Ex. 3 at 105.

- Exhibit 3 at 1-55, recording O.C.'s platelet counts from March 31, 2019 to February 24, 2020. These records reflect that all results from October 11, 2019 to February 24, 2020 were within the normal reference range. See generally Ex. 3 at 1-55 (documenting testing for O.C.'s platelet levels, with no test results from September 2019).
- Exhibit 5 at ¶ 27, an affidavit of O.C.'s parent Jared Cummings, stating:

In late January/early February 2020, O.C. was declared in remission of ITP. However, O.C. continues to have restrictions in playing on the playground and participating in other toddler activities. O.C. has further been discouraged from participating in any contact or high impact sports in the future for safety reasons.

The above medical entries establish that O.C.'s platelet counts fluctuated, but generally remained below normal for just under five months after onset (which in this case would likely be no earlier than March 27, 2019 – when O.C. first displayed the bruising after hitting her head), or until mid-August. O.C.'s platelet count later returned to the reference range for normal, as first revealed on October 11, 2019, and has stayed normal. But that was the first platelet reading since the August abnormal reading – with no evidence of *any* platelet testing for the intervening seven-plus week period. Thereafter, treaters deemed monitoring necessary.

Respondent asserts that the records show that "OC had normal platelet counts at all times after September 7, 2019," (relying on the March 7th date of vaccination as the likely start of onset – although the record does not establish this). Rule 4(c) Report at *6. Thus, Respondent argues, I cannot find in favor of a petitioner based on the claims of a petitioner alone, unsubstantiated by medical records or medical opinion, but must instead dismiss given the lack of substantiated severity. *Id.* (*citing* Vaccine Act Section 13(a)(1)).

Petitioners assert that the severity requirement is met, because although O.C.'s platelet count *seven* months after vaccination was in the normal range, her treating physician nevertheless characterized her platelet count as "*almost* normal," by implication suggesting that it was *not* normal. Response at *5. Petitioners also assert that O.C. had physical activity restrictions for over ten months, which has in other contexts been deemed evidence of a residual effect. See H.S. v. Sec'y of Health & Hum. Servs., No. 14-

1057V, 2015 WL 1588366 (Fed. Cl. Spec. Mstr. Mar. 13, 2015) (activity restriction due to vaccinee's vulnerable state after vaccine-induced syncope was part of treatment, and supported a finding that the severity requirement was met despite lack of outward symptoms of injury). Response at *1,7.

The severity requirement serves to exclude from compensation minor injuries. See Wright v. Sec'y of Health & Hum. Servs., 22 F.4th 999, 1002 (Fed. Cir. 2022). In cases where medical record evidence demonstrates residual effects that continue close to, but do not quite reach, the six month mark, I must closely analyze the record, as supported by other evidence like witness statements, to determine whether the severity requirement is met. While Respondent is correct that I cannot find in favor of a petitioner based on the petitioner's claims *alone*, that in no way precludes me from finding in favor of a petitioner based on a petitioner's testimony that *is supported* by other record evidence.

In many cases, severity may be established even where the medical record evidence suggests the underlying injury has mostly abated just prior to the six-month deadline. In *Silvestri v. Sec'y of Health & Hum. Servs.*, No. 19-1045V, 2021 WL 4205313 (Fed. Cl. Spec. Mstr. Aug. 16, 2021), for example, a Petitioner's last treatment was five months and three days after vaccination. Petitioner was not discharged from treatment at this appointment. Thereafter, he continued to self-treat, and provided evidence that his symptoms continued beyond that point. I found that the six month severity requirement was satisfied. I acknowledged that it was a close call, but emphasized the remedial nature of the Vaccine Program, in which "Petitioners are accorded the benefit of close calls." *Id.* at *4, citing *Roberts v. Sec'y of Health & Hum. Servs.*, No. 09-427V, 2013 WL 5314698 (Fed. Cl. Spec. Mstr. Aug. 29, 2013).

Similarly, in *Purtill v. Sec'y of Health & Hum. Servs.*, No. 18-0832V, 2019 WL 7212162 (Fed. Cl. Spec. Mstr. Nov. 12, 2019), a petitioner's last treatment appointment (for a SIRVA injury) was five months and three weeks after vaccination. By that date, Petitioner had improved significantly, but was still experiencing some pain and other symptoms. I reasoned that an injury that was causing pain at a week short of six months was unlikely to fully resolve within the following week. Thus, I found that the six month requirement was satisfied.

ITP, however, has been treated somewhat differently in the Program, since it is an insidious injury – diagnosable only through blood testing, but also very easily treated (when it is acute in nature). As an expert opined in *Wright*, vaccine-related ITP cases are generally acute (lasting less than one year). *Wright v. Sec'y of Health & Hum. Servs.*, No. 16-498V, 2019 WL 10610472, at *6 (Fed. Cl. Spec. Mstr. Jan. 18, 2019), *mot. for rev. granted and rev'd*, 146 Fed. Cl. 608 (2019), *rev'd*, 22 F.4th 999 (Fed. Cir. 2022). The

acute form of ITP can readily be remedied, making it easy to reverse the bruising and other facially-evident clinical symptoms of it – and, in turn, eliminate the injury itself, even though likely vaccine-caused, within six months of manifestation. *See Johnson v. Sec'y of Health & Hum. Servs.*, No. 14-113V, 2017 WL 772534, at *8 (Fed. Cl. Spec. Mstr. Jan. 6, 2017) (citing medical literature indicating that childhood acute ITP resolves within six months in more than 70 percent of affected children).

In *Wright*, the child's treating physician found that his ITP had resolved within three months of onset. *Wright*, 22 F.4th at 1003. But this fact alone underscores how this case is different – for there, the child's ITP had resolved well prior to the six month mark, and the Circuit found only that subsequent testing for platelet count drops was not *itself* a sequelae of the injury. Here, by contrast, the record does not contain evidence that O.C.'s ITP had resolved until *right around* the six-month mark. Thus, although I agree that certain matters deemed evidence of injury-related sequelae (i.e., the activity limitations or the treater's view that a normal platelet level was "not normal enough") are not good evidence of severity under *Wright*, it is not clear from this record that in fact O.C.'s ITP had reversed fully as of *any* date in September.

This matter presents a close case, but I find that it is more likely than not that O.C. continued to experience residual effects of her condition (as evidenced by abnormally low platelet levels) for at least six months – if barely. It can be inferred from the record evidence that O.C.'s platelet levels returned to normal *sometime* between late August and October 2019, when she was next tested again. But the specific date the "change" occurred cannot be pinpointed, given the absence of testing in September 2019. Nevertheless, O.C.'s levels remained low, if in normal ranges, when testing resumed, and were not immediately deemed high enough for treaters to stop measuring until at least February 2020. Ex. 3 at 1-7.

Under such circumstances - and although it is not *certain* that O.C.'s levels had risen to normal ranges after September 27, 2019 (a better six-month date under the facts of this case) – it is *at least as likely* that her levels had *not yet* gone into the normal range until sometime *between* mid-September and when next tested in October. There is no evidence to suggest the contrary in the record, and the absence of clear evidence establishing the date of the "turn" does not render my reasoning faulty.

This – plus the fact that persuasive caselaw urges special masters to decide close cases in a petitioner's favor – leads me to find severity in Petitioners' favor here. See Silvestri, 2021 WL 4205313, at *4 (denying motion to dismiss for failure to meet six month requirement and stating, "[a]t worst, this case represents a 'close call,' and in 'the Vaccine Program, petitioners are accorded the benefit of close calls'") (citing Roberts v. Sec'y of

Health & Hum. Servs., No. 09-427V, 2013 WL 5314698, at *10 (Fed. Cl. Spec. Mstr. Aug. 29, 2013); see also Purtill, 2019 WL 7212162, at *6; Grieshop v. Sec'y of Health & Hum. Servs., No. 14-119V, 2015 WL 4557620 (Fed. Cl. Spec. Mstr. June 5, 2015).

I again note that ITP is unlike other injuries discussed above, where treatment may linger for a time due to ongoing sequelae, making it easier to meet the severity requirement in such circumstances. Had the record established a return to normal platelet level readings *within* the six months from onset that did not fluctuate downward again, I would have been compelled to dismiss the case despite the kinds of arguments Petitioners make herein about ongoing monitoring – since *Wright* and other prior cases stand for the proposition that these are not true sequelae. But the testing "gap" in this case does not preponderantly establish a firm date the platelet levels changed, and I can reasonably infer severity was met given the circumstances. (Of course, because I find severity is barely met, Petitioners should expect any damages they receive to take into account the fact that O.C.'s ITP was ultimately not all that severe once treatment began).

Accordingly, based on the record as a whole, I find that it is more likely than not that O.C. suffered the residual effects of her condition for more than six months. Thus, the motion to dismiss is **DENIED**.

V. Scheduling Order

Respondent shall file, **by no later than <u>Monday, March 28, 2022</u>**, a status report indicating how he intends to proceed in this case or an amended Rule 4(c) Report.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master